(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain the following:

(i) Results of tests and assays on—

(*a*) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity; and

(*b*) The batch for potency, sterility, and pH.

(ii) Samples required:

(*a*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 5 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample (usually 1.0 milliliter) with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except if the steroid prevents solubilization, use 0.25 milliliter of the sample in lieu of 1 milliliter and proceed as directed in paragraph (e)(2) of that section.

(3) *pH.* Proceed as directed in § 436.202 of this chapter using the undiluted solution.

[44 FR 5880, Jan. 30, 1979, as amended at 50 FR 1504, Jan. 11, 1985; 50 FR 19920, May 13, 1985]

Subpart F—Dermatologic Dosage Forms

§ 448.510 Bacitracin dermatologic dosage forms.

§ 448.510a Bacitracin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin ointment is composed of 500 units of bacitracin per gram in a suitable ointment base. It may contain a suitable local anesthetic. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of bacitracin that it is represented to contain. Its moisture content is not more than 0.5 percent. The bacitracin used conforms to the standards described by § 448.10(a)(1).

(2) *Labeling.* (i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The bacitracin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The bacitracin used in making the batch: 10 packages, each containing approximately 1.0 gram.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for bacitracin zinc in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 1 percent potassium phosphate buffer, pH 6.0 (solution 1) and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of